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K120002

510(k) Summary

Regulatory Affairs Contact:	Muhamad Ansari Busse Hospital Disposables PO Box: 11067 75 Arkay Dr. Hauppauge NY 11788
Telephone:	631-435-4711 Ext: 254
Fax:	631-435-2849
Date Summary Prepared:	December 15, 2011
Product Trade Name:	I-Style Bone Marrow Aspiration Needle with T-Handle
Common Name:	Biopsy Instrument
Classification Name:	Class II, 21 CFR 876.1075, Product code KNW
Predicate Device:	I-Style Bone Marrow Aspiration Needle, **K061570** J-Style Bone Marrow Biopsy / Aspiration Needle with Snare-It Marrow Acquisition Cannula, **K110883**, Busse Hospital Disposables
Device Description:	The I-Style Bone Marrow Aspiration Needle with T-Handle consists of a 15G and 18G needle with a triple sharpened atraumatic tip stylet of corresponding size all made of AISI 304 Stainless steel. The needle has an ergonomic grip at whose base a Luer-Lock cone in fitted. The innovative element of the needle is a removable spacer, which indicates the depths the tip can reach. Using a depth stopper, easy adjustment of the needle length, making it easier to reach the tissue to be examined.

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Intended Use: The I-Style Bone Marrow Aspiration Needle with T-Handle is intended for aspiration of bone marrow.

Technological Characteristics:

The subject device has the same Technological Characteristics as a legally marketed predicate device. Except for the minor changes in the Design, which is the Quick Stylet locking handle, whereas in our new product is called T-Handle. Both are made out of AISI 304 Stainless Steel and ABS. The Subject device and the predicate device are intended for aspiration of bone marrow.

Summary of Testing:

All materials used in the fabrication of the I-Style Bone Marrow Aspiration Needle with T-Handle were evaluated through biological qualification safety tests.
The biocompatibility tests performed were:

- Cytotoxicity Test
- Intracutaneous Reactivity Test

Summary of Performance Testing: I-Style Bone Marrow Aspiration Needle with T-Handle has been tested for the following performance tests:

1. Fastening and perforation of the stylet tip on the needle entry point
2. Easiness of insertion of the cannula in the sampling area
3. Capacity Testing on the needle handle
4. Easiness and manageability of the adjustable spacer
5. Adequacy of the Luer-Lock connector and twisting capacity of the syringe for bone marrow aspiration
6. Inspection quantity control of the collected sample

These materials have met the testing requirements and were found to be acceptable for the intended use.

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Conclusion:

The above statements are accurate representations of the device Busse intents to market. Based on all the testing and comparison Busse believes the subject device is substantially equivalent to the predicate device. All data and information submitted in this premarket notification is truthful and accurate and no material fact has been omitted.

Official Correspondent: Muhamad Ansari (Signature)

Muhamad Ansari (printed name)

Title: Director of Regulatory Affairs

Date: 5/28/2012

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 2 6 2012

Busse Hospital Disposables, Incorporated
% Mr. Muhamad Ansari
Director of Regulatory Affairs
75 Arkay Drive
Hauppauge, New York 11788

Re: K120002
Trade/Device Name: I-Style Bone Marrow Aspiration Needle with T-Handle
Regulation Number: CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: II
Product Code: KNW
Dated: May 28, 2012
Received: May 31, 2012

Dear Mr. Ansarir:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin D Keith

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K120002

Device Name: **I-Style Bone Marrow Aspiration Needle with T-Handle**

The I-Style Bone Marrow Aspiration Needle with T-Handle is intended for Aspiration of Bone Marrow.

Prescription Use____X____ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

Neil R. Ogden for mxm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120002